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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. YOASH GOHIL Plaintiff/Relator, v. SANOFI U.S. SERVICES, INC. et al., Defendants.	CIVIL ACTION NO. 02-2964-ABB **FILED UNDER SEAL**

MEMORANDUM OF LAW IN SUPPORT OF RELATOR'S OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND REPLY TO DEFENDANTS' OPPOSITION TO RELATOR'S MOTION FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

Sir Arthur Conan Doyle once warned that "there is nothing more deceptive than an obvious fact." Aventis is banking on that.

In its cross-motion, Aventis ignores its own documents, its own compliance policies, its admissions of record, as well as the Anti-Kickback Act ("AKA") along with the contemporaneous OIG guidance on the relevant issues. It also disavows its expressed intent to "ease the burden of reimbursement" for doctors and "reduce obstacles to prompt third-party payment at predictable reimbursement levels to your practice when you prescribe Taxotere," as offered to doctors in its PACT Toolkit. SUMF at ¶ 14. And even after the Court warned Aventis that the Government's decision not to intervene in this case was irrelevant, Aventis tries to turn that into a dispositive issue,[1] along with the Government's dismissal of other, unrelated, dissimilar False Claims Act lawsuits.

Last, Aventis ignores the law and the facts by campaigning on its empty theme that PACT was meant to "help assist patients navigate the murky waters of reimbursement." *See* Br. at 6. Aventis offered PACT as a "value added" service to doctors to help them obtain insurance payments for off-label claims. It surveyed these customers to ensure their satisfaction with PACT's services. Its sales force and reimbursement managers ("RM") marketed PACT services

[1] Courts have repeatedly rejected the assertion that a decision not to intervene somehow signals a lack of merit. *See, e.g.*, *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) ("We do not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrong doing insufficient or the *qui tam* relator's allegations for fraud to be without merit. In any given case, the government may have a host of reasons for not pursuing a claim."); *U.S. ex rel. Chandler v. Cook County*, 277 F.3d 969, 974 n.5 (7th Cir. 2002) ("there is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in relator's attorney"); *Anderson v. McTish, Kunkle & Associates*, No. 4:04-cv-754, 2006 WL 1985762, at *1 n.1 (M.D. Pa. July 13, 2006) ("We are not permitted to draw any inference from the decision of the United States not to intervene in this case."); *cf. U.S. ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 21-22 (D.D.C. 2008) ("Indeed, assuming the government looked unfavorably upon each qui tam action in which it did not intervene would seem antithetical to the purpose of the qui tam provision – to encourage private parties to litigate on behalf of the government.").

directly to these customers (not to patients). PACT recouped money for claims denials and that money went directly to doctors. Aventis tracked these recoupments for the sales force, and it offered doctors free replacement drug if their off-label appeals were denied.

If even one purpose of PACT was to induce doctors to use and prescribe Taxotere, it runs afoul of the AKA.

II. LEGAL ARGUMENT

A. PACT IS ILLEGAL REMUNERATION

i. *PACT Violated OIG Guidance.*

Aventis's claim that its panoply of reimbursement services is not illegal remuneration because it comported with the existing OIG guidance is sophistry. First, PACT's services extend well beyond "serving as a clearing house for information regarding insurance coverage criteria and reimbursement levels," as described in the 2000 OIG opinion upon which Aventis relies. *See* Exhibit EEE, OIG Ad.Op.No. 00-10 at 7. This alone forecloses Aventis's argument that its provision of benefit verification and prior authorization services, reimbursement training, research on specific doctor billing inquiries, claims management, and drafting customized appeals, along with providing replacement product for denied appeals, is merely a "clearing house for information" as contemplated by this OIG guidance. *See* Ex. 1 at 62093 (Toolkit describing PACT service for doctors).

This is confirmed by the 2000 OIG opinion. It found that a pharmaceutical services program which "couples reimbursement support services with extended payment terms and, if necessary, an invoice credit or replacement vial of the drug implicates the federal Anti-Kickback Statute" because it confers an "independent financial benefit upon referring physicians by shifting the financial risk of unanticipated delays and denials associated with obtaining third-party payer reimbursement from the prescribing physicians to the company." *See* Exhibit EEE, OIG

Ad.Op.No. 00-10 at 7.[2] The OIG found that the invoice credit and replacement vial part of the program shifted the financial risk from the physicians to the drug company. *Id.* at 4. This offending reimbursement program did not even contain the extensive services for customized appeal drafting and processing that PACT does.

In short, both the 1992 OIG Special Fraud Alert as well as the 2000 OIG Advisory Opinion warned drug companies about the anti-kickback risks for reimbursement programs that provided far less services than the PACT program. These principles were reaffirmed in the OIG's May 2003 Guidance, noting that if a manufacturer provides "limited reimbursement support services in tandem with another service or program that confers a benefit on a referring provider" the arrangement would raise anti-kickback concerns. *See* Ex. FFFF at 23735. The OIG emphasized that if "services provided by the manufacturer eliminate any expense that the physician would have otherwise incurred (i.e., have independent value to the physician) …the arrangement may violate the Anti-Kickback Act." *Id.* at 23737. In sum, Aventis's PACT services provided a more extensive reimbursement guarantee, via its comprehensive appeal services and replacement benefit, as that found by the OIG in 2000 to raise anti-kickback concerns, and Aventis freely marketed these features to its customers.[3]

[2] The OIG declined to apply civil monetary penalties in this instance only because the program was limited to a new expensive prophylactic drug designed for members of low-income families that do not have financial resources, and there was little chance of overutilization as the patients are pre-qualified.

[3] In 2006 the OIG reaffirmed this position, finding that a DME supplier's provision of free reimbursement consulting services such as "reviewing claims, helping to appeal denied claims, providing assistance with issues related to assessing and documenting individual patient's medical records and medical justification for receiving particular products," along with reimbursement training, would "potentially confer substantial independent value" and "poses all the usual risks associated with kickbacks,". OIG Ad. Op. No. 06-16 at 4-5, *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-16A.pdf.

Aventis's claim that sales representatives could not discuss the free replacement product benefit of PACT with doctors is both misleading and belied by its own documents. First, the sales force routinely handed out the PACT Toolkits, which explained the free product features of the PAP program. The free drugs were not only available to "uninsured" patients via PAP, but also to "underinsured" patients, whose Taxotere claims were denied. SUMF at ¶ 85. As part of this Toolkit, the replacement drug was initiated via PAP qualification forms that were provided to physicians with the criteria for "insurance without coverage for Taxotere." *Id.*; *see also* Supplemental Declaration of Nicholas C. Harbist ("Supp Harbist Decl") Ex. 93, Brown Dep. T334-T338. As RM Brown admitted, the appeal denials and provision of replacement product by way of enrollment in PAP was "understood" by the sales force and replacement product updates "went to the rep." *Id.* at T326-T329. Second, Aventis's documents show that, in practice, the sales force repeatedly promoted this replacement guarantee to doctors. SUMF at ¶¶ 67, 69, 74 (e.g., "while [Dr. Chan] is a valued customer I had explained to them that providing drug would done for an uninsured patient or in the case of an appeal being denied"). Even RM Brown advised doctors about the replacement drug benefit. SUMF at ¶ 70. Aventis cites no specific document or policy that prohibited the sales force from discussing the replacement drug benefit with doctors. Indeed, it is clear that the sales force was trained on PACT's replacement benefit, and both the sales force and the PACT specialists freely promoted this replacement guarantee to doctors. SUMF at ¶ 67.

Similarly, to support its argument there was no reimbursement guarantee (Br. at 20-21n. 16), Aventis makes much of the fact that to obtain replacement drug, doctors had to report any subsequent claim reimbursement and return any overpayment. But in the words of RM Brown, Aventis "has never really enforced this 'rule.'" Supp. Harbist Decl. Ex. 104, SAVGOH –

00400257191 (June 26, 2000 email from Rebecca Hayes to Loreen Brown regarding lack of process within PACT program for billing providers after obtaining reimbursement).

As a last resort, relying on the Government's dismissals in *United States v. EMD Serono, Inc* (E.D. Pa.) and other cases, *see* Ex. A., Aventis attempts to equate the comprehensive reimbursement services offered by PACT to the limited services "assist[ance] for physicians with completion of insurance documents, such as benefit verifications and prior authorizations forms. *See* Ex. A at 3. The nature and extent of the PACT services are simply not qualitatively or quantitatively the same and, more importantly, the Government noted that the *Serono* cases were brought by a "professional relator, who filed eleven *qui tam* cases for profit and obtained its information under "false pretenses." *See id*. at 1, 6. The Government concluded, after a thorough investigation, that the Relator's sweeping "allegations lack adequate support and are unlikely to yield any recovery." *Id.* at 16. Not so here. In sum, the *Serono* allegations concerning "provision of educational information and instructions to patients" are a far cry from the extensive reimbursement services and replacement guarantee provided to physicians as outlined herein. *Id.* at 16. Despite the Government's dismissals in *Serono*, another district court refused to dismiss a FCA case brought by professional relators alleging free nursing and reimbursement support services, noting that the Government's contentions that "these allegations—which they acknowledge assert a classic violation of the AKS—'conflict with important policy enforcement purgatives of the government's healthcare programs'…is curious at best." *United States ex rel. Cinznhca, LLC v. UCB, Inc*., 2019 WL 1598109 at *4 (S.D. Ill. Apr. 15, 2019).

ii. *PACT Services were a Thing of Value.*

Alternatively, Aventis argues that PACT provided physicians with nothing more than "nominal value" (Br. at 21), while at the same time admitting that its RMs believed that the PACT services provided "value to physicians." Aventis Response to SUMF at ¶ 130. But Aventis RMs

admitted that PACT support services "provided value" to doctors such that they were "unparalleled in our industry" and described those services to doctors "value added." SUMF at ¶¶ 80-83, 92, 130. In its September 2003 monthly report to Aventis sales management, a PACT RM described its recoupment of specific denied claims as a "substantial service to this physician's office and also relieved the physician's staff from having to spend many hours or even days fighting for payment." SUMF ¶ 60. And by virtue of PACT's services, doctors received substantial payments from Medicare by way of appeal recoupments. SUMF ¶ 137, Ex. 88. So much for Aventis's claim that there is no evidence showing that any physician in fact received substantial value from PACT. Indeed, Aventis RMs admitted that certain PACT services reduced the doctors' administrative expenses. *See* Supp Harbist Decl Ex. 94, Hayes Dep. T243.; Ex. 93 Brown Dep. at T150, 161-63. And Aventis's suggestion that drafting an appeal is a *de minimis* endeavor is just plain wrong. Two former Healthbridge employees said the exact opposite. *See* SUMF ¶¶ 49-50, Ex. 17 ¶ 9; *see also* Ex. 40 (PACT advised Aventis that it has "taken the authoring stage out of the mix for offices…based on those inundating administrative tasks that take so long.").

Last, Aventis's argument that Relator failed to quantify the exact value of PACT services provided to any one physician not only misstates the evidence, but is irrelevant. Heeding Aventis's directive "to take the burden away from the office," PACT reported that doctors' offices rely on PACT "as an extension of their workforce, to get the job done, efficiently and effectively." SUMF ¶¶ 125-26. Further, Aventis's RMs reported that specific doctors were impressed with PACT's services, in one case noting that a doctor "would not have to spend the time following up on the authorization request [and that] was very important to her." SUMF ¶¶ 60 & 127.

This coupled with the evidence that Aventis initially paid its PACT vendor a set fee per call for each physician request for service and budgeted over $1,000,000 in 2002 as well as

$3,500,000.00 in 2003 for Health Bridge to run PACT, and paid these vendors in accordance with the contracts, is more than sufficient evidence that the PACT services were a "thing of value." SUMF ¶¶ 119-22. As importantly, there is no requirement in anti-kickback law that requires proof of the exact value of the kickback, as long as the free services provided qualify under the broad definition of "remuneration" (remuneration means "anything of value in any form or manner whatsoever" 56 Fed. Reg. 35952, 35958 (July 29, 1991)). Moreover, there is no requirement that a doctor actually receive the thing of value, as the statute outlaws both "offers" as well as the "payment" of remuneration. 42 U.S.C. § 1320(a)-7b(b)(2)(B).

iii. *Aventis Intended to Induce Sales and Prescriptions*.

Aventis claims that it had no intent to "improperly influence physicians' prescribing decisions," and that its "driving motivation" was to "assist patients" who had a medical need to access Taxotere. Br. at 23. In so arguing, it ignores the "one purpose rule" under the AKA and attempts to import a *quid pro quo* requirement into the statute. None of these propositions exist in AKA law.

First, it is well settled that to prove an AKA violation, the Government need only prove that "one purpose" of the remuneration is to induce referrals. It is of no import if Aventis had some other purpose, even a benevolent one. *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985); *United States ex. rel. Arnstein v. Teva Pharms. USA., Inc.*, 2019 U.S. Dist. LEXIS 35148, at *9 (S.D.N.Y. Feb. 27, 2019)(citing cases). Similarly, the physicians' *ex post* denials of improper influence or inducement in Exhibits K and R are of no moment because the AKA does not require evidence of a *quid pro quo*. There is no requirement that Aventis attempt to bring about the results by means of a specific conversation or expressed condition. *Id.* at *10. Accordingly, Aventis's argument that the PACT program "had no influence on doctors' prescribing decisions" is an attempt to rewrite the settled case law. *See United States ex rel. Greenfield v. Medco Health*

Solutions, Inc., 880 F.3d 89, 97 (3d Cir. 2018) (plaintiff need not "prove a kickback actually influenced a patient's or medical professional's judgment"). All of Aventis's other arguments, that: (1) there is no evidence that Aventis conditioned doctors' receipt of PACT services on a doctor prescribing specific quantities; and (2) there is no evidence that Aventis threatened or ceased providing PACT services because a doctor failed to write a minimum number of prescriptions (Br. at 25), all run afoul of these well-settled principles.

On the other hand, the evidence of inducement in this case is compelling and unrebutted. Aventis admits that its sales training materials and its employees referred to PACT as a "value-added" service. SUMF ¶ 80. And in its Toolkit marketed to doctors, Aventis tied PACT support services directly to increasing insurance payments to doctors "when you prescribe Taxotere." SUMF ¶ 84. Its RMs who oversaw PACT's services were considered part of the sales team and reported to the directors of sales and marketing, with the job requirement of supporting the sales force. SUMF ¶¶ 87-88. The RMs regularly visited physicians' offices and attended free dinner programs with the sales force to market PACT's services. SUMF ¶ 90. The sales force used the RMs "to sell [] value-added services" and described PACT as an "excellent value-added program." SUMF ¶ 92. Part of the RMs' "key goals" were to build future business, and the marketing director even praised an RM as an "important contributor" to the top performing sales region. SUMF ¶ 93. Like the sales force, the RMs received sales-based bonuses in their regions. SUMF ¶ 91. That the enhanced PACT+ services were conceived to author appeals for Aventis's "largest customers" so that those customers could obtain reimbursement for off-label uses confirms that PACT's intent was to increase revenue for its "largest" customers. SUMF ¶¶ 94, 96-97. Also, Aventis tracked PACT's overall return on investment (ROI), including the ROI for the RMs' visits to physicians'

offices, and conducted customer satisfaction surveys of its doctors to monitor PACT's success. SUMF ¶¶ 103, 104, 105 and 106.

Aventis's attempt to avoid the impact of this powerful evidence by arguing that the RMs' reporting structure and bonus program was based "on convenience" and "competence" ignores its own records. Br. at 24 n.18. Its explanation for its managers' repeated emphasis on PACT ROI and customer surveys submitted to doctors as merely reflecting its intent "to ensure that the patients received the benefits" ignores reality. Further, its attempt to distance itself from its PACT vendors' expressed intent to assist Aventis "maximize product sales revenue" and "increase the physician's incentive to prescribe" via PACT similarly does not reflect reality or the record. SUMF ¶¶ 111-15. Aventis RM Brown conceded that all of the Healthbridge vendor proposals were received and accepted without objection. SUMF ¶ 116.

Last, even if the Court bought into Aventis's mantra that PACT, along with its Alternative Funding ("AFP") component, was created to benefit Medicare beneficiaries, rather than to improperly influence physicians' prescribing habits, PACT still violates the AKA. Providing free services for the benefit of patients to ensure they had access to Taxotere still implicates the AKA because OIG guidance and AKA law similarly prohibit renumeration to influence Medicare beneficiaries. Simply put, there is no safe harbor for providing free services to patients to induce them to use Taxotere.

Aventis was aware of the risks and chose to proceed and enhance the PACT Program despite the clear and incontrovertible guidance issued by the OIG – this is undeniable.[4] Just after the implementation of the AFP component of PACT in mid-2002, on October 10, 2002, Aventis was specifically advised of OIG Advisory Opinion No. 02-13, which opined on whether "a manufacturer of a drug or device … [may] subsidize copayments incurred by financially needy [Medicare] beneficiaries[.]"[5] Supp. Harbist Decl. Ex. 105, SAVGOH-00400393177 at 178. *See also* OIG Advisory Opinion No. 02-13 *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2002/ao0213.pdf at 4. Ultimately, the OIG concluded that such an arrangement would violate the AKA because of the likelihood that the arrangement would generate prohibited remuneration. *Id*. at p. 6. In reaching its conclusion, the OIG reasoned that:

> 1. The proposed arrangement is squarely prohibited by statute because: a) the arrangement results in a patient's physician receiving full payment for prescribing the drug at issue; and b) the availability of financial assistance would be improperly advertised;

[4] Aventis was informed that the OIG no longer took the position that "while anti-kickback and beneficiary inducement concerns were implicated, the OIG would not pursue enforcement efforts against a manufacturer that offered product replacement to physicians whose claims for an expensive, injectable drug were denied by insurers." Supp. Harbist Decl. Ex. 105, SAVGOH-00400393177 at 178. To be sure, in light of revised OIG Guidance, HealthBridge specifically recommended that Aventis choose an alternate path to meet its alleged "objective to provide a user-friendly approach to assisting patients … [that] are challenged to fund the co-pay portion of their therapy due to limited income and/or lack of third party payment assistance." *Id.* at 179.

[5] Under this scenario, the drug manufacturer proposed to establish and solely fund a "foundation" which would then use the manufacturer's funds to "pay all or part of the cost-sharing amounts incurred by privately insured and Medicare patients using [the drug] who are deemed to be financially needy." While the arrangement contemplated by OIG Advisory Opinion No. 02-13 was limited to a drug cost-sharing arrangement between a manufacturer and patients, the assistance offered by Aventis's AFP component was more egregious. More specifically, Aventis sought to provide patients with consulting services to obtain assistance for basic needs, including housing, utilities, transportation and groceries, among other things. For this reason, the OIG's prohibition on patient assistance applies with equal force to Aventis' AFP component of PACT.

2. The arrangement poses the typical risks of fraud and abuse because the drug at issue would receive obvious financial advantages over competing drugs, including a physician's ability to receive full financial reimbursement rather than bear the risk of cost-sharing obligations;

3. Assistance programs that subsidize Medicare cost-sharing may be extremely profitable to drug manufacturers.

Id. at 5.

All of these AKA concerns are equally present in PACT and the AFP. After being notified of this OIG guidance, Aventis was specifically cautioned that its "program structure as modeled … may represent a significant risk to Aventis" because "the proposed arrangement, by which [] [Aventis] would subsidize all or part of certain Medicare beneficiaries' Part B cost-sharing amounts … ***would clearly implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse***." Supp. Harbist Decl. Ex. 105, SAVGOH-00400393177 at 178 (emphasis added). Similarly, Aventis's intent to induce patients to use Taxotere by providing PACT reimbursement services, along with the AFP benefits, still implicates the AKA, as Aventis would illegally profit from its alleged "benevolence." *See, e.g.*, August 2002 OIG Special Advisory Bulletin "Offering Gifts and Other Inducements to Beneficiaries," *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf (explaining that only nominal gifts or free services not to exceed $10 per item and $50 annual limits may be offered to beneficiaries without violating the AKA).

In sum, as long as one purpose was to induce sales or referrals from doctors, the fact that Aventis may have had another purpose is of no consequence. The illegal inducement purpose is clear from Aventis's own records.

B. THE PACT KICKBACK IS MATERIAL TO THE GOVERNMENT'S PAYMENT DECISION

While the Supreme Court explained in *Escobar* that the materiality standard is "demanding" and "rigorous," Aventis overstates *Escobar*'s impact on the facts of this case. Courts look to several factors in determining whether conduct is material to the Government's decision to pay: whether the Government "expressly identif[ies] a provision as a condition of payment," *U.S. ex rel. Escobar v. Universal Health Servs., Inc.*, 136 S. Ct. 1989, 2003 (2016); whether "the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement," *id.*; and whether the requirements at issue go to "'the very essence of the bargain,'" *id.* at 2003 n.5 (quoting *Junius Const. Co. v. Cohen*, 178 N.E. 672, 674 (N.Y. 1931)). This analysis requires "'a holistic approach . . . with no one factor being necessarily dispositive." *U.S. ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017) (quoting *U.S. ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016)).

Courts have long recognized that violations of the AKA are material. *See, e.g., U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817-18 (S.D.N.Y. 2017) ("[T]he Court has no trouble concluding that compliance with the AKS is a 'material' condition of payment,"), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 330 (S.D.N.Y. 2014) (observing that "[c]ourts have long held" that "compliance with the AKA is a precondition to the payment of Medicare and Medicaid claims"). AKA violations are material because "[t]he Government does not get what it bargained for when a [party] is paid by [a federal health care program] for services tainted by a kickback." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011). This conclusion is supported by the facts that: (i) violation of the AKA has been a felony since 1972, *see* 42 U.S.C. § 1320a-7b(b); and (ii) the

AKA provides explicitly that "a claim that includes items or services resulting from a violation of [the AKA] constitutes a false or fraudulent claim." *Id.* § 1320a-7b(g). *Cf. U.S. ex rel. Arnstein v. Teva Pharms. USA, Inc.*, 2019 WL 1245656 at *29 (S.D.N.Y. Feb. 27, 2019) (observing that the Government's decision to intervene in a parallel pending FCA case premised on AKA violations "strongly indicates that violations arising out of speaker program AKA violations [both before and after the 2010 PPACA Amendments] affect the Government's decision to pay").

Aventis apparently does not dispute that compliance with the AKA is a condition of payment for Government health care programs, a strong indicator of materiality.[6] Nevertheless, the record establishes that the Government does not pay kickback-tainted claims. Nor could it: (1) as far back as 1992 in its Special Fraud Alert, the OIG warned companies about the ramifications of the AKA and its specific application to pharmaceutical prescription drug marketing schemes.[7] The OIG advised that kickbacks pose a danger to patients because the offering of remuneration "may interfere with the physician's judgement in determining the most appropriate treatment for a patient" and spelled out various kickback related marketing practices that "may increase the … government's cost of reimbursing suppliers for products"; (2) in the

[6] *See, e.g.*, *Wilkins*, 659 F.3d at 313-14; 42 C.F.R. § 423.505(h)(1) (requiring Medicare Part D plan sponsors to certify compliance with all "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to applicable provisions of the . . . anti-kickback statute"); *see also* CMS Form 855s (Medicare providers must sign this form, stating they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute"), *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855s.pdf. The form 855 along with its attestation that doctors comply with all Medicare laws has been in existence since at least 2001.

[7] OIG Special Fraud Alert (May 1992), reprinted at 55. Fed. Reg 65372, 65375 (Jan. 19, 1994). The OIG documents and DOJ Statements of Interest are public records of "a public office" that "set [out] the office's activities" and, therefore, are admissible under F.R.E. 803(8). *See In re MBTE Prods. Liab. Litig.*, 591 F. Supp. 2d 259, 277 n.3 (S.D.N.Y. 2008).

2003 OIG Guidance, pharmaceutical manufacturers were advised to "be aware of the federal anti-kickback statute and the constraints it places on the marketing and promotion of products reimbursable by the federal healthcare programs, including, but not limited to, Medicare and Medicaid." The 2003 Guidance also made clear that the OIG viewed AKA violations as grounds for "exclusion from the federal healthcare programs," as well as for "liability under the False Claims Act." 68 Fed. Reg. 23731-01 at *23734 (May 5, 2003); (3) Aventis's own policies prohibited kickbacks to induce sales and prescriptions and even prohibited the customer assistance programs like PACT.[8] SUMF ¶¶ 134-38. *See infra* at 19-21. Indeed, all of the PACT vendor contracts included anti-kickback compliance provisions. Ex. ZZ, YY; (4) even in the Advisory Opinions relied upon by Aventis, the OIG specifically warned that "no opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting or related conduct" (*see* Exs. EEEE, GGGG), thus, warning pharmaceutical companies about the anti-kickback risks and suggesting that improper billing based upon AKA violations would be enforced through the FCA; (5) in DOJ's Statements of Interest in a pharmaceutical kickback cases, it unequivocally stated that "Park Davis' violation of the AKS in inducing the prescriptions would affect the government's decision to pay the prescriptions written by the doctors receiving the kickbacks from Park Davis." 2003 WL 24314328, DOJ SOI, May 23, 2003, at 13. The DOJ relied on FCA cases predicating liability on

[8] During the relevant timeframe, Aventis' hospital customers that purchased Taxotere were required by law to sign HCFA-2552 forms, which prohibits payment of claims procured by a kickback. *United States ex. rel Schmidt v. Zimmer, Inc.* 386 F.3d 235 (3d Cir. 2004) (upholding a FCA kickback claim and noting that a certificate of compliance with federal law is a prerequisite to eligibility under the Medicare program, citing 42 C.F.R. 413.24 (f)(4)(iv)).

violations of the AKA dating back to 1994. *Id*. at 17n.10;[9] (6) between 1997 and 2004, the Government took FCA enforcement actions against pharmaceutical companies under the FCA based upon AKA violations. *See* Supp Harbist Decl Exs. 106a-f; (7) CMS denied Taxotere claims for lack of medical necessity, and Aventis's RMs knew the Government would deny medically inappropriate claims. SUMF ¶ 137, Supp Harbist Decl Ex. 93, Brown Dep. at 126-27; Supp Harbist Decl Ex. 94, Hayes Dep. at T192. That is precisely why they implemented the PACT+ enhanced appeal services. Supp Harbist Decl Ex. 93, Brown Dep. at T146, T150.

Instead of acknowledging these facts, Aventis argues that governmental payors "consistently reimbursed claims for which the PACT Program provided assistance with knowledge of the program's involvement." Br. at 27. But the issue is not whether the Government reimbursed claims for which it knew the PACT program provided some "informational" assistance, as Aventis claims; rather, the issue is whether the Government reimbursed those claims despite actual knowledge of the panoply the PACT program services provided to physicians *free of charge* with the intent to induce prescriptions, and that resulting prescriptions and claims were tainted by violations of the AKA. None of the evidence cited by Aventis establishes that the Government paid claims despite actual knowledge of the full scope of PACT and that it was intended to induce sales and prescriptions. *See United State ex. rel. Spay v. Caremark*, 875 F.3d 746, 763 (3d Cir.

[9] Similarly, in the DOJ SOI in *United States ex rel Bidani v. Lewis* (10/25/02), Supp Harbist Decl Ex. 107, the Government stated that not only was compliance with the AKA a prerequisite to payment, but emphasized that the defendant's argument that the Government was "willing and content to pay claims for services that are known to have resulted from the illegal payment of kickbacks blatantly contradicts the entire statutory scheme and the evidence that Congress never intended to subsidize providers for buying patient referrals with kickbacks." *Id*. at 12-13. Further, the Government noted that it has repeatedly emphasized that AKA violations give rise to FCA liability, citing cases dating back to 1994. *Id*. at 13 n.6. *See also* Ex. 107 at 6-7, DOJ SOI in *United States ex. rel. Schmidt v. Zimmer* (5/11/01), *supra* ("The United States would not have paid for *any* [kickback] tainted services").

2017) (requiring "actual knowledge" of the violations). Even RM Brown admitted that the Government was never told that the PACT services were provided to the doctors for free, or that PACT contained a free replacement drug benefit for doctors. Supp Harbist Decl Ex. 93, Brown Dep. T392-T395, T414-T415.[10]

Similarly, the fact that the Government continued to reimburse claims even after it learned of Relator's allegations has no bearing on materiality. This same argument was rejected in *Escobar* on remand and in numerous other cases. 846 F.3d 103, 112 (1st Cir. 2016); *see also, U.S. ex rel. Lutz v. Berkeley HeartLab, Inc.* No. 14-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017) (defendants had failed to show that the government knew "that any claims were *actually tainted* by an illegal kickback scheme.") (emphasis in original). In *Lutz*, the court noted that "it took…years of investigation to determine whether any defendant had…violate[d] the AKS and, in turn, the FCA," and that the government "does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing." *Id*. Also, the fact that defendants argued there was no violation undercut their concurrent argument that the government continued to reimburse claims despite actual knowledge of violations. *Id*.; *accord United States ex rel. Brown v. Pfizer*, 2017 WL 34435, at *11 (E.D. Pa. Apr. 12, 2107); *Polansky v. Exec. Health Inc*., 2018

[10] Aventis brushes off the vial replacement program as "limited" and used only in a "few instances." *See* Br. at 20. Once again, Aventis's own documents belie its argument. *See* Ex. 122, SAVGOH – 00400084070-81 (showing that hundreds of Taxotere vials were replaced through the PACT program from 2002-2004 alone; this document also shows other services provided by PACT, including services used to obtain reimbursement for off-label uses of Taxotere).

WL 1403433, at *7 (E.D. Pa. Mar. 18, 2018) (noting Medicare often "would have no way of knowing" whether any particular claim failed to comply within regulations).[11]

But even if the Government did have actual knowledge of AKA violations here, its continued reimbursement of Taxotere would not undercut a finding of materiality. The Government may suspend payments to health care providers based on credible allegations of fraud, but the regulation provides several good cause exceptions. *See* 42 C.F.R. § 405.371(a), (b). For example, as the DOJ explained in its Statement of Interest in *Teva*, "the government may find that good cause exists not to suspend payments if beneficiary access to items or services would be jeopardized such that suspension may pose a danger to life or health, suspension may compromise an investigation, or suspension is not in the best interests of the health care program." *See* Supp Harbist Decl Ex. 108, DOJ Statement of Interest in *United States ex. rel. Arnstein v. Teva Pharms. USA., Inc.* (9/14/18) at *12 (citing 42 C.F.R. § 405.371(b)(1)). "The more essential [the good] is to an important government interest, the less the government's continued payment weighs in favor" of establishing that a particular violation is not material. *U.S. v. Public Warehousing Co.*, No. 05-2968, 2017 WL 1021745, at *6 (N.D. Ga. Mar. 16, 2017).

Aventis cites only two cases to support its argument; neither is an AKA case, and both are readily distinguished on other grounds as well. Unlike this case, *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017) involved information reporting deficiencies that were not alleged to violate any statute or regulation, and the relator "essentially concede[d] that CMS would *consistently reimburse* the[] claims with full knowledge" of them. *Id.* at 490 (emphasis in original).

[11] Aventis's reliance on *United States ex rel Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392 (D.N.J. 2019) is not helpful to its position. In *Simpson*, the court noted that AKA violations were "a well settled trigger of FCA liability," noting that both the AKA and the Medicare "reasonable and necessary requirement" were conditions of payment. *Id*. at 412-13. These designations weigh heavily in favor of finding materiality. *Id*.

And *U.S. ex rel. Spay v. CVS Caremark Corp.*, *supra*, involved a pharmacy benefit manager's innocuous use of "dummy" physician identifiers to submit electronic claims when proper numbers could not be obtained. The court dismissed the case because the dummy identifiers "were intended [solely] as a technical, formulaic way of preventing a computer program from denying legitimate claims for reimbursement and payment for prescriptions that were actually disbursed to Medicare recipients." 875 F.3d at 765. There was no allegation any prescription had been wrongly induced, or that any claim was not legitimate; and the government had actual knowledge of *all* the facts and circumstances underlying the supposedly false claims, and yet took no action to deny payment on those claims. *Id*. at 763-64.

Applying the "holistic approach," it requires no leap to conclude that Aventis's AKA violations were material to the Government's payment decision. Compliance with the AKA was a condition of payment, as the AKA violations denied the Government the benefit of its bargain; the Government consistently enforced the AKA through the FCA and Aventis knew this. There is no evidence that the Government continued to reimburse claims despite "actual knowledge" the AKA was being repeatedly violated by Aventis.

C. THERE IS UNDISPUTED EVIDENCE OF WRONGFUL INTENT OF AVENTIS MANAGERS TO INDUCE SALE AND REFERRALS

Aventis's scienter argument is an exercise in revisionist history, as it ignores the contemporaneous evidence showing the wrongful intent of its managers.

First, Aventis's reimbursement team, including RM Brown, as well as other Aventis employees and management, regularly received or forwarded notifications about the illegality of giving anything of value to physicians to induce prescriptions under the AKA. *See*, *e.g.*, Supp Harbist Decl Ex. 109, SAVGOH-00400331984 ("PATIENT ASSISTANCE PROGRAMS MAY VIOLATE KICKBACK RULE….") (emphasis in original); Supp Harbist Decl Ex. 110,

SAVGOH-00400164780 (certain co-pay assistance programs and "co-pay foundations violated the anti-kickback statute"); Supp Harbist Decl Ex. 111, SAVGOH-00400079150 (warning of the illegality of "bribing doctors and pharmacists to favor [a company's] products"); Supp Harbist Decl Ex. 112, SAVGOH-00400180511 (defendants can be convicted under the AKA "even if inducing patient referrals constitutes just 'one purpose'—but not necessarily the overriding goal—of the financial relationship"); Supp Harbist Decl Ex. 113, SAVGOH-00400203726 ("CMS' guidance, however, stops well short of giving the OK on anti-kickback rules for manufacturer PAPs"); Supp Harbist Decl Ex. 114, SAVGOH-00400236927 ("the courts have identified several potential aggravating considerations that can be useful in identifying arrangements at greatest risk of prosecution. In particular, manufacturers should ask the following questions, among others, about any problematic arrangements or practices they identify: Does the arrangement or practice have a potential to interfere with or skew, clinical decision-making?") (emphasis in original); Supp Harbist Decl Ex. 115, SAVGOH-00400325966 ("The restrictions on patient assistance programs essentially mirror anti-kickback rules designed to prevent Medicare beneficiaries from being steered towards particular providers or drugs").

Many of these same individuals, including RM Brown, were also privy to compliance advice regarding "[redacted]" for patient assistance programs. *See* Supp Harbist Decl Ex. 116, SAVGOH-00400166001.00006 *et seq.* This compliance advice quoted at length from the AKA, and explained that patient assistance programs implicate "[redacted]." *See id.*, SAVGOH-00400166001.00008. The compliance guidance explained that [redacted]

[redacted]

[redacted]" *Id.*

Finally, the guidance explained that whether a patient assistance program raises AKA concerns depends on, among other things:

1. "[redacted]";
2. "[redacted]";
3. "[redacted]"; and
4. "[redacted]" *Id.*, SAVGOH-00400166001.00007-08.[12]

Aventis's compliance policies were consistent with these multiple warnings, as well as the existing OIG guidance, and stated that any "customer assistance programs": (1) "may not be tailored to a specific individual or entity customers' business, but should be of a more general educational nature"; and (2) "may not be a substitute for activities that are part of the customer's costs of carrying out its business as a healthcare provider." Ex. 87. Those same policies prohibited Aventis from "providing a consultant to advise customers which is intended to specifically enhance some aspect of the customer's business, including billing practices…." *Id.* at 00611. While it may be true that neither Aventis nor the PACT vendors ever entered into a formal "consultant" agreement with any doctors, Aventis puts form over substance. Aventis concedes PACT provided

[12] Should Aventis now claim that its employees did not actually read these materials, that would not be an excuse. When a defendant claims a "lack of guilty knowledge," knowledge may be inferred if he "deliberately closed his eyes to what otherwise would have been obvious to him. One cannot avoid responsibility for an offense by deliberately ignoring what is obvious." *United States v. Stewart*, 185 F.3d 112, 126 (3d Cir. 1999).

reimbursement research assistance and training to physicians. Ex. 3, SRFA 6 and 8. That is the *sine qua non* of a "consultant."[13]

Other Aventis business ethics policies prohibited kickbacks more generally. *See* Supp Harbist Decl Ex. 95, Corrigan Dep. T110:1-20. According to one, which incorporated the AKA by reference:

> the basic prohibition of the law has been interpreted very broadly to apply to arrangements if "one purpose" of the payment is to induce prohibited referrals or product recommendations, even if that purpose is not the primary purpose of the arrangement. The anti-kickback law therefore potentially may be an issue whenever Aventis provides anything of value to customers or other persons in a position to influence the utilization of Aventis products or services.

Supp Harbist Decl Ex. 117, D00949, Policy 514 Antitrust Compliance for Medicare and Medicaid Fraud Abuse. Notably, Aventis's corporate designee testified that compliance training on these policies was "endemic" at Aventis and "all departments" underwent training on compliance policies. *See* Supp Harbist Decl Ex. 95, Corrigan Dep. T117:1-T118:17. Aventis even concedes that all of the PACT vendor contracts contained clauses prohibiting violations of the AKA. Br. at 31.

Moreover, even RM Brown admitted that she was familiar with Aventis's policies and that they—and the law—prohibited the provision of kickbacks to healthcare providers. *See* Supp Harbist Decl Ex. 93, Brown Dep. T100:11-T101:21. But despite her knowledge of the AKA,

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[13] Similarly, Aventis attempts to distance itself from its own ethics policy by claiming it did not provide "physicians with billing assistance" or otherwise act as "consultant." Br. at 30. But, in doing so it ignores RM Brown's testimony that: (1) she typically met with billing staff during doctor visits, Harbist Decl. Ex. 93, Brown Dep. at 54, 72-73; (2) PACT was "to help the doctor's office get paid," *Id*. at 212, and usually dealt with office managers or billing specialists, *Id*. at 186, and (3) she described how the reimbursement managers acted as a consultant to doctors' billing staff. *Id*. at 239-240. Even the Toolkit advertised "payer-specific billing and coding information" as part of PACT's services. Ex. 1 at 62093. Aventis admits it provided "coding advice" (Br. at 30), and cannot deny that such coding is used on the CMS-1500 bill. Aventis SUMF at ¶ 66.

Aventis's ethics policies, and multiple, specific warnings about the AKA risks of PAPs, she directed and promoted the PACT program with impunity—and for the unlawful purpose of inducing sales.[14] And even though she, as reimbursement manager, was technically in a non-sales position, she admitted:

- It was her purpose to help doctors solve their reimbursement problems and help them get paid (*id*., T71-T72 and T124-T126);
- PACT alleviated doctors' concerns about using Taxotere off-label (*id*., T264-T265);
- It was "one of [her] key goals, as directed by management, to build future business" "[f]rom a reimbursement standpoint" (*id*., T64:1-8);
- According to her 2001 performance evaluation by Marty Duvall, Aventis's head of marketing, she was an "important contributor to the West Region," from a "sales" perspective (*id*., T59:2-T61:16, T65:14-T66:1);
- According to her 2001 performance evaluation, she "eliminated barriers to coverage and made it easier for providers to choose Taxotere" (*id*., T66:2-7);
- The PACT Program was designed as a "key differentiator" between Taxotere and Taxol, which had reached the market before Taxotere (*id*., T79:13-T80:7; *see also id*., T130:16-T132:13, T254:12-T256:7);
- Aventis's reimbursement team was "committed to impacting field sales by assisting [] customers by providing value-added services and information" (*id*., T88:7-17);
- Aventis management expressed to her that she was expected to "assist field sales by assisting customers" (*id*., T94:12-18);
- 70% of the bonuses for her, Furman, and Scelfo were based on sales (*id*., T98:23-T99:15);
- It "was the intent of the PACT program to help the doctors' offices get paid" (*id*., T125:21-T126:10);
- Her "responsibilities over the PACT program facilitated field sales" (*id*., T196:2-16);

[14] The AKA specifically prohibits the offering or payment of renumeration to induce a person "to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good…." 42 U.S.C. Section 1320a-7b(b)(2)(B).

- Aventis's RMs held lunch and dinner presentations for doctor's offices, and sales representatives attended and paid for the events (*id*., T240:10-T241:5);

- Upon receipt of an email from a sales manager that stated PACT's "successes" in recouping $20,000 for a doctor "clearly fit our differentiation message...Good $elling," she reported to PACT and her boss "keep up the good work!" Ex. 86. She understood the sales manager's reference to "$elling" "means they make money" Ex. 93 at 258.

- One of her goals as reimbursement director was to "grow current business" (*id*., T523:21-T524:7); and

- She "helped the sales team by ensuring unimpeded reimbursement" (*id*., T525:15-17).

Given RM Brown's unequivocal admissions in writing and testimony that at least one purpose of PACT was to boost sales[15] and referrals, and her and other employees' knowledge that it was unlawful to provide anything of value to healthcare providers to induce the purchase and prescribing of Taxotere, Aventis cannot deny that it knowingly and willfully violated the law through PACT. RM Brown's boss, Marty Duvall, lavished praise on RM Brown for a job well done, and he, too, knew of the legal ramifications of PAPs. *See*, *e.g.*, Supp Harbist Decl Ex. 110, SAVGOH-00400164780. Aventis also cannot deny that it either ignored or rejected the warnings and compliance advice it received about patient assistance programs. The Third Circuit has

[15] Aventis' description of the intent of the AFP is particularly disingenuous. In her recommendation to approve the AFP funding to her boss, RM Brown noted that the AFP "would provide several benefits": (1) reduce the number of vials/tabs provided through PAP; (2) assist providers in obtaining reimbursement for their services through other funding sources; and (3) provide patients with coverage for drugs other than Taxotere. She opined that "the ROI would be well worth the cost," noting that "patients and providers will benefit from this value-added program." Supp. Harbist Decl. Ex. 103, Brown Dep. Ex. 28 at SAVGOH-00600048182. The attached proposal by Healthbridge makes clear that the AFP program "will compliment Aventis' sales and marketing efforts to maximize patient third-party coverage, maximize product sales and minimize patient assistant program expenditures." *Id*. at 8186. In her presentation to the sales force, RM Brown emphasized the benefit to the doctors in that they would receive reimbursement for the treatment they provide "so they [the doctors] would receive the administration fee as well as the drug reimbursement fee." Supp. Harbist Decl. Ex. 93, Brown Dep. at 370. The company approved the Healthbridge AFP proposal. *Id*. at 373.

recognized that "[d]octors are supposed to make decisions based on medical necessity, not their own fiscal interests; for that reason 'taking…kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal.'" *United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015) (quoting *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998)). Likewise, experienced pharma employees could hardly expect that it would be legal to provide physicians with free consulting services marketed to increase physicians' revenue, thereby increasing Taxotere sales. Yet that is exactly what the reimbursement team did, and with management's blessing.

And it was not just RM Brown. Danielle Scelfo, RM Brown's assistant reimbursement manager, testified that she was "very familiar with kickbacks" and "absolutely" would have followed any Aventis policy regarding kickbacks. *See* Supp Harbist Decl Ex. 96, Scelfo Dep. T14:10-14, T64:16-T65:16. Yet, she trained the Aventis sales force on PACT, referring to its services as "your tools and resources in the field" to help their doctor "customers navigate through the reimbursement process." *See id*., T105:22-T107:18; and T117-18; *see also* Supp Harbist Decl Ex. 118, SAVGOH-00400193803, September 2004 Initial Reimbursement Workshop by Danielle Scelfo (Ex. 8 to Scelfo Dep.) at SAVGOH-00400193806 & SAVGOH-00400193830-33.

On one occasion, a sales representative asked RM Scelfo how she could address a physician who was encouraging the use of generic Taxol over Taxotere because it had a better reimbursement structure. RM Scelfo acknowledged that the generic Taxol had "a significant economic advantage for physicians," but noted that the sales representative could promote both the clinical advantages of Taxotere as well as the PACT reimbursement services that were "unparalleled in [the] industry." *See id*., T119:13-T121:4; *see also* Supp Harbist Decl Ex. 119, SAVGOH-04300205530-31. She even acknowledged that she was "advocating" to this sales representative to redirect focus to the

"clinical advantages…and to list out the assistance programs we offer patients who may have any challenges getting coverage or reimbursement." Supp Harbist Decl Ex. 96, Scelfo Dep. T122-T126. She testified that she intended that sales representative communicate the PACT benefits "to the patients," but then admitted that the sales force only speaks with the doctors, not the patients. *Id.* at T126.

RM Brown was copied on this email exchange and, sure enough, she forwarded the exchange to her boss, Marty Duvall. *See id*. And rather than responding to warn that Aventis could not market the free services of PACT to increase sales, as director of marketing he confirmed the use of PACT as a sales tool - "[PACT] is intended to help our customers and patients have access to these products…[e]ducating customers on what is available from Aventis to support their use of Aventis products is a very important mission." *See id*. Duvall, of course, was familiar with AKA rules as he signed several of the PACT vendor agreements, which contained AKA compliance clauses. *See, e.g.*, Exs. 78, 79, 26.

If that is not enough, Lesley Lacey, the Parexel manager who serviced Aventis's PACT program, testified that RMs Brown and Hayes told her they expected PACT analysts to "go the extra mile for their customers" and "help as much as [they] could." *See* Supp Harbist Decl Ex. 97, Lacey Dep. T23:12-T24:9. Ms. Lacey also confirms that the purpose of PACT was "to provide reimbursement support services for [Aventis] and their customers to eliminate reimbursement barriers" and "help the doctors get paid by insurers for Taxotere use." *Id*., T52:20-23, T53:22-T54:12. She also confirms that RMs Hayes and Brown admitted that reimbursement "was important to the doctors." *Id*., T86:3-23. Finally, she recalls that she was removed from Aventis's PACT because she was not "producing the results and obtaining reimbursement" for doctors to the satisfaction of Hayes and Brown. *Id*., T97:17-T99:11.

John Seman, the general manager for the medical marketing group at Parexel, and later CEO of Healthbridge, also explained that PACT was a mercantile endeavor. He confirmed, for example, that the January 2002 Healthbridge PACT proposal to Aventis was meant to "complement Aventis' sales and marketing efforts to maximize patient third-party coverage, maximize product sales and minimize patient assistant program expenditures." *See* Supp Harbist Decl Ex. 98, Seman Dep. T53:11-18. The proposal goes on to spell out that Healthbridge's comprehensive appeal services designed to "distinguish a product and increase the physician's incentive to prescribe". *Id*., 60-61. With this proposal Seman testified that Healthbridge was "trying to complement [Aventis's] sales efforts by providing reimbursement services." *Id*., T54:23-T55:1. Finally, Seman explained that the January 2002 Healthbridge proposal was directed to RM Brown. *See id*., T48:15-23, and "incorporates the elements that [she] requested." *Id*. at T49. He did not recall any objections to this proposal from Aventis. *Id* at T51.

Next, RM Brown was directed by her boss that management wanted "to have a couple versions" of the PACT appeal letters available, "so that if more than one appeal is filed with a specific payer, the letters don't all look the same." *See* Ex. 19; *see also* Supp Harbist Decl Ex. 120, SAVGOH-00400060400 ("[redacted]."); Supp Harbist Decl Ex. 99, SAVGOH-00400099635 (another email regarding the "two versions" of the prostate appeal letter, with "privilege" redactions in the email, even though counsel is not copied). Aventis embarrassingly tries to sweep this surreptitious activity under the rug by claiming that "a few appeal templates were prepared to provide patients with different form letters for the various levels of appeal." Br. at 31n.24. That is an *ex post* rationalization. First, the email (Ex. 19) says nothing about "various levels of appeal." Rather, it is obvious from the face of the email that the purpose of having

multiple versions of the same letter was to avoid suspicion by the insurers so "the letters don't all look the same." Second, the "two versions" of the prostate appeal letter that were created are directed to the first level of appeal; not for the successive appeals. Ex. 99 at 9635-40. Last, the patients were not the ones submitting appeals letters, the doctors or PACT vendors were. In the same regard, when PACT analysts handled appeals, according to Aventis, they held themselves out as acting on behalf of physicians, rather than Aventis. *See* Supp Harbist Decl Ex. 97, Lacey Dep., T135:7-17. Aventis frequently attempts to take shelter in patient care and spin the conversation from sales to patients care.[16] So be it. But surely the benevolent Aventis knows that a terminal patient could not care less about the "form" or "verbiage" of an appeal letter she likely would never see.

Aventis further claims that there is no evidence it knew that PACT was providing reimbursement support for medically unnecessary off-label claims. *See* Br. at 30n.22. But in Ex. 36, RM Hayes edited and approved an off-label medical necessity letter after she was apprised by PACT that "the office didn't [not] have good office notes to support the use of Taxotere. The physician tried Taxotere as a last resort before the patient died in February." Thus, it is clear that RM Hayes, who copied RM Brown, was approving the submission of appeals where the office notes did not support the use of Taxotere. Moreover, the appeal letter that was submitted did not specifically indicate to Medicare that the physician tried Taxotere as a "last resort before the patient

[16] With respect to Aventis's claim that its RMs analyzed reimbursement issues on a case-by-case basis so that they could ensure that PACT's services were lawful, the exhibits cited demonstrate the opposite. In fact, Exhibit EEE shows that RM Brown authorized a sales representative to provide doctors samples to keep them happy for use at "the physician's discretion" ("If this office is upset, you can always give them a few sample vials in the meantime"). But she admitted that under the law samples could not be billed to insurance carriers. *See* Supp Harbist Decl Ex. 93, Brown Dep., T324:12-15. Similarly, in Exhibit FFF, RM Brown merely explains the reimbursement guarantee to an Aventis manager (for those patients whose insurance denies the claim, "PACT+ can help (either with free drug or appeal assistance)."

died." More importantly, medical necessity letters written by PACT were routinely submitted without review and approval by doctors, despite the representation in those letters that it was the doctor's "professional, medical opinion" that Taxotere was an essential therapy for the patient. SUMF ¶ ¶ 50-52, Ex. 36. So it was Aventis or its PACT agents that were in reality vouching for the medical necessity of Taxotere.

Finally, Aventis makes the juvenile claim that "everybody else does it," attempting to demonstrate that its misconduct was somehow endorsed by the industry.[17] Regardless, Aventis again fails to distinguish between traditional patient assistance programs and its PACT program. Aventis did maintain a "PAP" to assist needy patients, but PACT was distinct and aimed to assist physicians' bottom lines, not patients.[18] Second, Aventis's reliance on *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195 (3d Cir. 2006) to negate scienter falls flat. *Colkitt* merely reiterates longstanding Third Circuit precedent that "universal industry practices are not outcome determinative" as to corporate state of mind, and "[e]ven a universal industry practice may still be fraudulent." *Id*. at 219. *Colkitt* also addressed whether a certain transaction was illegal in light of "uncertainties in the securities industry" at the time. *See id*. at 212, 219. Here, Aventis points to

[17] Throughout its cross-motion, Aventis relies on studies, periodicals, and documents regarding other companies' PAPs. Because Aventis is not introducing these materials as documents relied on or explained by an expert, they should all be disregarded as hearsay. *See, e.g., Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 873 (E.D.N.Y. 2018) (articles "inadmissible on summary judgment"); *Barraford v. T & N Ltd.*, 988 F. Supp. 2d 81, 87 (D. Mass. 2013).

[18] A "Patient Assistance Programs Update" circulated internally among Aventis employees in 2007 is telling. This document refers to three traditional PAP models, all of which are limited to providing free drugs or drug subsidies to patients, whether directly from the manufacturer or through a charitable foundation. *See* Supp Harbist Decl Ex. 121, SAVGOH-04300176638-39. That is not PACT. PACT provided free reimbursement services directly to physicians. Notably, even these "softer," patient-focused PAPs were designed to "eliminate patient out-of-pocket expense *as a barrier to physician prescribing behavior*" and "generate corporate goodwill." *See id*. (emphasis added). And even these "softer" PAPs raised anti-kickback concerns. *See id*., SAVGOH-04300176646-47, SAVGOH-04300176662-71.

no uncertainty as to whether providing free, value-added services that included replacement product to induce prescriptions was unlawful under the AKA.[19]

III. CONCLUSION

Aventis's repeated admonition to the Court (Br. 23) that any finding that PACT violates the AKA would threaten long standing industry practice rings hollow, given the OIG's repeated warnings to drug manufacturers about AKA risks for free reimbursement services, DOJ's regular enforcement of the AKA via the FCA, the court decisions, which have declined to dismiss FCA cases based upon a drug manufacturer's reimbursement programs, and Aventis's violation of its own AKA policies.

For these reasons, Relator respectfully requests that the Court deny Aventis's cross-motion and grant Relator's Motion for Partial Summary Judgement as to the PACT kickback FCA claims.

Respectfully submitted,

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Dated: August 26, 2019

[19] Citing to *In re Tyson Foods, Inc. Sec. Litig.*, 155 F. App'x 53, 57 (3d Cir. 2005), Aventis suggests that Relator cannot proceed on a theory of "collective intent" to establish Aventis's scienter in an FCA case. *Tyson Foods* does not so hold.

CERTIFICATE OF SERVICE

I, STEPHEN M. ORLOFSKY, hereby certify that on August 26, 2019, I served via Federal Express, email, and/or secure file share the foregoing Memorandum of Law in Support of Relator's Opposition to Defendants' Cross-Motion for Partial Summary Judgement and Reply to Defendants' Opposition to Relator's Motion for Partial Summary Judgment and accompanying papers on the following counsel of record:

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